PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

GILSON et al.

Appln. No.: 10/058,828

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For: EMBOLIC PROTECTION DEVICE

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Examiner: Uyen T. Ho

DECLARATION OF PAUL GILSON, EAMON BRADY, PADRAIG MAHER, DAVID VALE, AND CHAS TAYLOR

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Paul Gilson, Eamon Brady, Padraig Maher, David Vale, and Chas Taylor do declare and state as follows:

1. We are the inventors of the subject matter claimed in the above-identified United States patent application.
2. This declaration is submitted in support of a request for interference with U.S. Patent Application Serial No. 09/723,003, filed November 27, 2000, pursuant to 37 C.F.R. §41.202(a).
3. We have read and understand the two counts which are proposed for the interference that are described herein.
4. Subsequent to January 1, 1996, and prior to March 5, 1998, we conceived of the invention defined by Count 1 in the Republic of Ireland.
5. Subsequent to January 1, 1996 and prior to March 5, 1998, we conceived of the invention defined by Count 2 in the Republic of Ireland.
6. All events referred to herein occurred subsequent to January 1, 1996.

7. From a time prior to March 5, 1998, until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, we and others working at our direction were engaged in continuous, diligent activity directed to achieving a reduction to practice of the invention defined by Count 1 in Ireland and in the United States.

8. From a time prior to March 5, 1998, until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, we and others working at our direction were engaged in continuous, diligent activity directed to achieving a reduction to practice of the invention defined by Count 2 in Ireland and in the United States.

9. Our activities relating to conception, diligence and reduction to practice of the inventions defined by Count 1 and Count 2 are described in more detail as follows.

I. BACKGROUND

10. At the time of the events described herein, MedNova was a start-up company located in Galway, Ireland. In the present declaration, MedNova and its wholly-owned subsidiary, Salviac, Ltd. are referred to as "MedNova."

11. During the events described herein, Paul Gilson was employed by MedNova as Executive Director and Chief Scientific Officer. During this period, Paul Gilson was responsible for Operations, Research and Development, Regulatory Affairs and Quality Control.

12. During the events described herein, Eamon Brady was engaged by MedNova as Research and Development Manager. During this period, Eamon Brady was responsible for MedNova's embolic filter protection device development project.

13. During the events described herein, Padraig Maher was employed by MedNova as a Research and Development Engineer.

14. During the events described herein, David Vale was employed by MedNova as a Senior Development Engineer.

15. During the events described herein, Chas Taylor was employed by MedNova as Executive Director and Marketing Director. During this period, Chas Taylor's responsibilities at MedNova included clinical studies, marketing and sales.

16. During the events described herein, John O'Shaughnessy was employed by MedNova as Executive Director and CEO of MedNova, and participated in meetings and conferences concerning the design of the embolic filter system.

17. During the events described herein, Mairsil Claffey was the Quality Assurance and Regulatory Affairs Manager of MedNova, and participated in meetings and conferences concerning the design of the embolic filter system. On February 13, 1998, Mairsil Claffey sent an email message to Paul Gilson (Exhibit 100) identifying her schedule for returning from maternity leave. It was stated that she would work a half day either Thursday, February 19, 1998, or Friday, February 20, 1998, followed by half days on Wednesday, February 25, 1998, through Friday, February 27, 1998, and then half days the week of Monday, March 2, 1998, through Friday, March 6, 1998.

18. At the time we conceived of the inventions defined by Count 1 and Count 2, MedNova's research and development activities were directed to two potential product lines, one of which was an embolic protection device within the scope of Count 1 and Count 2.

19. From February of 1998, until April 8, 1998, nine researchers employed by MedNova, including the inventors, were engaged in a continuous effort to produce a practically useful embolic protection device within the scope of Count 1 and Count 2.

20. From February, 1998, until April 8, 1998, Paul Gilson and Chas Taylor were responsible for ex vivo evaluations of prototype embolic filter protection

devices and methods; Paul Gilson had responsibility for development of guidewires for use with the filter system; Eamon Brady had responsibility for the filter development project; Padraig Maher was wholly engaged as an R and D engineer with responsibilities including producing embolic protection devices; and David Vale was wholly responsible for the retrieval catheter used to retrieve the filter element from the artery after performance of carotid artery angioplasty procedures.

21. From February, 1998, until April 8, 1998, we worked closely with other employees of MedNova who were engaged in making and testing the components of the embolic protection filter and the system required to carry out the methods defined by Count 1 and Count 2.

22. The individuals referred to herein were working together in a team structure. There was crossover, but described herein are the specific responsibilities of the various people involved. The employees working on the embolic filter protection device and method were Keith Ryan, a Research and Development Engineer who was generally responsible for PTFE shrink development work, which was necessary to make the delivery catheters used to transluminally insert the filter into a vessel; Shivaun O'Rourke, a Quality Assurance Engineer who had duties including test development and evaluation of prototype devices, including filter elements, delivery and retrieval catheters; Susan Eighan, a Manufacturing Engineer who had duties including catheter manufacturing line setup, and Nitinol forming and sac bond process development used in producing the embolic filter element; Mairsil Claffey, Mary Gallagher, Shivaun O'Rourke and Jon Hager, who were members of the quality assurance team and regulatory team and had duties including vendor approval, receiving goods system, documentation and reviewing and approving sterility procedures for producing the embolic protection device;

and Steven Horan, a Research and Development Engineer who had duties including filter sac ("balloon") development.

23. In order to demonstrate that an embolic protection device is practically useful in performing the methods defined by Count 1 and Count 2, we developed a number of components that may be required to carry out the procedure defined by the counts, including, for example: an embolic filter element, having appropriately sized holes for filtering emboli from the blood while maintaining blood flow in the vessel, and a suitable material and configuration for the supporting frame and struts that will ensure deployment to engage a wall of the vessel; a suitable guidewire size and configuration, such that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element; a delivery catheter for transluminally inserting the filter element into a vessel, which permits reliable deployment of the filter element so that the struts and filter sac expand to engage a wall of the vessel; and a retrieval catheter which permits the filter element containing emboli to be withdrawn from the vessel.

24. Because the device is intended to be used in interventional procedures including carotid artery angioplasty, we ensured the structural integrity of each of these components during performance of such procedures; provided suitable methods for sterilizing each component; and determined dimensions such as the size of the filter sac holes which will capture emboli of concern, while maintaining sufficient blood flow, and the thickness of the filter sac which is required to provide structural integrity.

25. We have reviewed and understand the following proposed Counts 1 and 2.

Proposed Count 1 **(Gilson Claim 97)**
A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal stop,

and a filter element having a capture ring disposed for translation on the guide wire proximal of the stop; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element to engage a wall of the vessel, the filter element filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element.

Proposed Count 2 **(Gilson Claim 98)**
A method of filtering emboli from blood flowing through a vessel, the method comprising: providing a guide wire having a distal region including a distal stop, and a filter element disposed for translation on the guide wire proximal to the distal stop, the filter element comprising a plurality of self-expanding struts having a filter sac affixed thereto; transluminally inserting the guide wire and filter element into a vessel; deploying the filter element so that the struts and filter sac expand to engage a wall of the vessel, the filter sac filtering emboli out of blood flowing through the vessel; advancing a treatment device along the guide wire to treat a portion of the vessel proximal to the location of the filter element, rotation or distal translation of the guide wire relative to the filter element not displacing the filter element; further comprising retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element.

II. CONCEPTION

26. Prior to March 5, 1998, we conceived of an embodiment of our invention that is disclosed in Irish Application No. 97 0789, filed on November 7, 1997, of which benefit is claimed in the present application.

27. Our conception of the following limitations of Count 1 is corroborated by Irish Application No. 97 0789:

> Irish Application No. 97 0789 discloses a filter element that provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24).
>
> IE '789 discloses a device that is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5).
>
> IE '789 discloses a device that consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft being disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18, which is threaded over a guidewire (page 16, lines 6-8).
>
> In accordance with IE '789, the clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8).
>
> In accordance with IE '789, the filter is deployed into the vessel and will capture emboli (page 12, lines 8-11); the deployed filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24).
>
> In accordance with IE '789, the deployed filter is placed distal to the site of the lesion being treated and will capture emboli that are generated or dislodged during balloon inflation and stent placement, a balloon and a stent being treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 4-11; page 19, lines 10-17; Claims 23, 24).

> Because in IE '789 the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter: it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the shaft thus does not displace the filter element.

28. Prior to March 5, 1998, we conceived of an embodiment of our invention that is disclosed in a drawing from David Vale's laboratory notebook which is attached as Exhibit 1. In all of the exhibits attached to this declaration, dates and information relating to dates have been redacted.

29. Exhibit 1 is an accurate description of an embodiment of our embolic protection system as drawn by David Vale and as that embodiment existed prior to March 5, 1998. We called the system "Neuroguard", and Exhibit 1 illustrates the details and dimensions of a delivery catheter having a Y-shaped Touhy Borst adapter and a catheter shaft of wound springwire having a Teflon® (*i.e.*, polytetrafluoroethylene or "PTFE") heat-shrink cover. The delivery catheter is used to transluminally insert a filter element into a blood vessel, and to deploy the filter element in the blood vessel.

30. The filter element is described as a "Chronoflex"™, (i.e. polyurethane which is used to form a membrane)balloon filter sac mounted on a polyimide tube support.

31. The polyimide tube has an outer diameter of 0.0179″ and an inner diameter of 0.0145″.

32. The "Chronoflex" balloon filter is illustrated in an expanded configuration, in which a "balloon" filter having a main body thickness of 0.002″ is attached by

adhesive to the polyimide tube and to a Nitinol framework which supports the filter sac.

33. The balloon or membrane filter is shown with large orifices at the proximal end of the filter, which permit the entry of blood containing emboli, and with smaller orifices at the distal end of the filter, which filters emboli from blood flowing through the filter and out the smaller orifices.

34. Nitinol is a self-expanding material, and in the illustrated embodiment the self-expanding filter sac is shown in its deployed configuration, expanded by a supporting Nitinol framework which has four struts attached to a proximal ring which is adjacent to the larger filter openings at the proximal end of the filter.

35. Within the inner lumen of the polyimide tube, which has an inner diameter of 0.0145″, is optionally disposed a guidewire having a maximum shaft diameter of 0.014″ to allow for rotation and translation of the guidewire relative to the filter element.

36. Exhibit 1 thus confirms that we conceived of a filter element which is advanced along a guidewire, and that we considered that rotation or distal translation of the guidewire relative to the filter element would not displace the deployed filter element. In the disclosed embodiment, the guidewire may be rotated or distally translated relative to the polyimide tube without displacing the filter mounted on the tube, because the inner diameter of the polyimide tube is larger than the diameter of the guidewire.

37. In Exhibit 1, the guidewire extends through the inner lumen of the filter element polyimide tube, and extends beyond the distal end of the filter, which is disposed near the distal end of the guidewire.

38. Exhibit 1 also refers to an interface of the filter element polyimide tube and treatment devices including a balloon catheter and a stent balloon catheter, which are indicated to have a minimum lumen interior diameter of 0.020″.

39. As confirmed by Exhibit 1, we conceived that these conventional treatment devices may be advanced along the guidewire over the polyimide tube, which has an outer diameter of 0.0179″.

40. The NeuroGuard embodiment of our invention as shown in Exhibit 1 meets at least the following limitations of Count 1 as summarized in the following table.

Neurogard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown, *e.g.*, in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014″. The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145″, and is thus disposed for translation on the guidewire proximal of the distal end of the guidewire. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending from a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789. The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Exhibit 1 are inserted into a vessel to treat a portion of the vessel, and are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145″, and the guidewire has a maximum shaft outer diameter of 0.014″, Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

41. Prior to March 5, 1998, we conceived of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal

diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end, and thus is a stop within the scope of Count 1.

42. In our conception of the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted is designed to rotate and translate on the guidewire, because the guidewire has a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″).

43. Prior to March 5, 1998, we realized that a small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

44. In a meeting between Paul Gilson and Padraig Maher prior to March 5, 1998, the undesirable friction was discussed with the potential for improvement focusing on the polyimide material and the use of low viscosity silicone. The need for the test wires for further evaluation was also discussed. Exhibit 102 is a copy of an entry in Paul Gilson's scheduler reflecting this meeting.

45. In a conference call design review meeting prior to March 5, 1998, Chas Taylor referred to a solution to this problem by using a custom guidewire, having a thinner proximal portion on which the filter element polyimide tube support is mounted. He referred to a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″.

46. Our conception is corroborated by an email describing the meeting, having a date before March 5, 1998, which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy. This email was sent before March 5, 1998, to Susan Eighan and Mairsil Claffey, and is attached as Exhibit 3.

47. Prior to March 5, 1998, we appreciated that our invention of using a stepped guidewire, having a distal end portion with a diameter greater than the inner

diameter of the polyimide tube (0.0145″) would serve as a distal stop, which limits distal translation of the filter on the guidewire. The stepped guidewire has a distal end diameter larger than the 0.0145″ inner diameter of the polyimide filter support.

48. Prior to March 5, 1998, Paul Gilson had a discussion with Richard Dalton of Lake Region Manufacturing Co. regarding a stepped guidewire. Exhibit 103 is a copy of an entry in Paul Gilson's scheduler reflecting this discussion and referring to a "step up guidewire."

49. Our appreciation of the distal stop function of the stepped guidewire is further corroborated by a memorandum describing a meeting of Chas Taylor with a vascular radiologist, Peter Gaines, that took place prior to March 5, 1998, attached as Exhibit 5. Exhibit 5 describes a question from Dr. Gaines, asking how to remove the guidewire if the tip of the guidewire needs to be reformed, to permit better steering of the guidewire in the vessel if there is any difficulty in passing the lesion after the guidewire and filter are inserted in the vessel. The document states that because of the stepped guidewire configuration, the guidewire cannot be removed from the polyimide support of the filter element when in place in a vessel. Chas Taylor indicated that the best solution was to remove both the filter and guidewire from the vessel, to reform the guidewire outside the vessel, and to transluminally reinsert both the guidewire and the filter into the vessel through the guiding catheter.

50. A copy of this memorandum was provided prior to March 5, 1998, to the inventors and to John O'Shaughnessy.

51. Prior to March 5, 1998, we decided that the optimal stepped guidewire configuration for use with a polyimide tube filter support having an inner diameter of 0.0145″ was a custom guidewire having a proximal diameter of 0.013″, which would permit rotation and distal translation of the filter on the proximal portion of the guidewire, and a distal end diameter of 0.016″, which

would act as a distal stop. Paul Gilson met with Tom Kleist of Lake Region Manufacturing Co., a guidewire manufacturer, prior to March 5, 1998. Paul Gilson specified to Tom Kleist the stepped guidewire that he envisioned. Tom Kleist prepared a handwritten sketch of the guidewire that Paul Gilson described to him, and sent the sketch from Lake Region's Dun Loaghaire sales office in Ireland to Lake Region offices in Minnesota to obtain a price quote for the guidewire. Exhibit 98 is a copy of that handwritten sketch which shows a 0.013″ outer diameter guidewire with an abrupt transition to a 0.016″ outer diameter coil.

52. Our conception is further corroborated by an order for the custom stepped 0.013″/0.016″ guidewire, which was placed with a guidewire manufacturer, Lake Region Manufacturing Co., prior to March 5, 1998. This order is confirmed by a facsimile from Tom Kleist of Lake Region, dated prior to March 5, 1998, and an invoice from Lake Region, showing that the custom stepped 0.013″/0.016″ guidewire was shipped to MedNova and received prior to March 5, 1998. (Exhibit 7).

53. Prior to March 5, 1998, we and our co-workers at MedNova constructed an embodiment of a prototype filter device and system which was designated as the "NeuroShield Mark 1" embolic filter protection system. Exhibit 90 is a true and accurate photograph of a filter element of a NeuroShield Mark 1 embolic filter protection system prototype from January 1998 on a support wire.

54. The prototype NeuroShield Mark 1 filter system corroborates our conception of the following limitations of Count 1, as shown in the following table:

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18.

> The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145″, and the filter may be disposed for translation on a guidewire proximal of the distal stop of the guidewire. The polyimide tube support would prevent the filter from translating distal of the guidewire stop.
>
> The balloon filter is shown in Exhibit 90 in its deployed configuration, as described in Irish Application No. 97 0789, as it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.
>
> Treatment devices such as a balloon catheter or a stent balloon catheter disclosed in Irish Application No. 97 0789 would be inserted into a vessel to treat a portion of the vessel, and would be advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.
>
> The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145″, and the proximal region of a guidewire for use therewith would have an outer diameter of 0.013″. Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element would not displace the filter element. The guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element.
>
> The filter system shown in Exhibit 90 would be used in the methods described in Irish Application 97 0789, in which the guidewire is first steered across the lesion, through the filter support, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft would not displace the filter element.

55. Prior to March 5, 1998, we conceived of an embodiment of our invention meeting each limitation of proposed Count 2.

56. Like Count 1, Count 2 requires that the guidewire have a “distal stop.” Count 2 also recites the step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the filter element. Count 2 further states

that the filter element comprises a plurality of self-expanding struts having a filter sac affixed thereto.

57. Our conception of the following limitations of Count 2, is corroborated in Irish Application No. 97 0789, filed November 7, 1997, as shown in the following table:

Disclosure of Irish Application No. 97 0789
Irish Application No. 97 0789 discloses a filter element that provides a pathway for blood and has means for capturing and retaining undesired embolic material released during a surgical procedure (page 11, lines 19-24). IE '789 discloses a device that is used in an over the wire transcatheter configuration, in which the clinician will cross the lesion with a steerable guidewire (page 12, lines 3-5). IE '789 discloses a device that consists of a filter attached to a shaft that can run over the primary crossing guidewire (page 12, lines 11-13); the shaft is disposed for translation on the guide wire proximal of the distal end of the guidewire, for example, substrate shaft 33 in Figs. 11-15 and 18 which is threaded over a guidewire (page 16, lines 6-8). Fig. 18 of IE '789 discloses a filter element having a plurality of Nitinol shape-memory struts, formed to remember an open shape, having a balloon filter affixed to the support (page 18, lines 9-14); the membrane filter fabric may be bonded to the supporting spoke framework (page 15, lines 25-31) or attached over the Nitinol frame (page 17, lines 6-7). In accordance with IE '789, the clinician will cross the lesion with a steerable guidewire, and the filter is then threaded over the guidewire and placed distal to the site of the lesion being treated (page 12, lines 4-8). In accordance with IE '789, the self-expanding filter of Fig. 18 is deployed in the vessel and will capture emboli (page 12, lines 8-11); the expanded filter element will occlude the vessel except for the path or paths provided through the filter (page 12, lines 21-24). In accordance with IE '789, the deployed filter will capture emboli that are generated or dislodged during balloon inflation and stent placement, which

are treatment devices advanced along the guide wire to a position proximal to the location of the filter (page 12, lines 8-11; page 19, lines 10-17; claims 23, 24). In accordance with IE '789, because the shaft or hollow support element (page 12, lines 14-18) on which the filter is mounted is not fixed to the guidewire (page 12, lines 11-13), rotation or distal translation of the guidewire relative to the filter element does not displace the filter element. The guidewire moves independently from the filter: it is first steered across the lesion, and the filter is then threaded over the inserted guidewire and deployed in the vessel (page 12, lines 3-11). During retrieval, the filter can be withdrawn either with the guidewire or over it (page 16, lines 23-25). The filter is attached to a shaft that can run over the prior crossing guidewire (page 12, lines 11-13), and rotation or distal translation of the guidewire relative to the filter support shaft thus does not displace the filter element.

58. Our conception of the following limitations of Count 2 is disclosed and corroborated by Exhibit 1, which is discussed above and is a page from the notebook of inventor David Vale that was made prior to March 5, 1998, as shown in the following table:

Neurogard Details and Dims.
The CHRONOFLEX balloon filter is used in the method disclosed in Irish Application No. 97 0789, as shown in Fig. 18. Guidewire having a maximum shaft outer diameter (O.D.) of 0.014″. The balloon filter is disposed on a polyimide tube having an inner diameter (I.D.) of 0.0145″, and is thus disposed for translation on the guide wire proximal to the distal end of the guide wire. Self-expanding Nitinol shape-memory struts support the filter sac, shown with large proximal holes and small distal holes, in expanded configuration. Exhibit 1 illustrates the filter polyimide tube support and guidewire extending through a delivery catheter that is transluminally inserted into a vessel, as described in Irish Application No. 97 0789. The self-expanding CHRONOFLEX filter is shown in deployed configuration, as described in Irish Application No. 97 0789, to engage a

> wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed.
>
> Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which are inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 1, they are advanced along the guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789.
>
> Because Exhibit 1 describes the inner lumen of the polyimide tube as having a diameter of 0.0145″, and the guidewire has a maximum shaft outer diameter of 0.014″, Exhibit 1 discloses that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element.

59. Prior to March 5, 1998, we conceived of a guidewire having a distal stop located at the distal end of the guidewire; a filter element disposed for translation on the guidewire proximal to the distal stop; and the method step of retracting the guide wire in a proximal direction to cause the distal stop to abut against the polyimide tube support of the filter element.

60. Prior to March 5, 1998, we conceived of a dual-diameter or "stepped" guidewire with a distal end region having a diameter greater than the proximal diameter, which permits the filter element to translate distally and rotate on the guidewire proximal of the thicker distal end, but prevents translation of the filter distal to the thicker distal end, and thus is a stop within the scope of Count 2.

61. In our conception of the filter element shown in Exhibit 1, the polyimide tube on which the balloon filter is mounted was designed to rotate and translate on the guidewire, because the guidewire had a smaller diameter (0.014″) than the inner lumen of the polyimide tube (0.0145″).

62. Prior to March 5, 1998, we realized that a small clearance between the guidewire and the polyimide tube caused undesirable friction between the guidewire and the tube.

63. An email from Padraig Maher on the subject "Review of Polyimide tubing functionality," which was sent prior to March 5, 1998, to Eamon Brady, Fergal Farrell, John O'Shaughnessy, Mairsil Claffey; Susan Eighan, Ruth Houlihan, and Paul Gilson, is attached as Exhibit 2.

64. As Padraig Maher disclosed in Exhibit 2, we appreciated that the lumen was too tight for the guidewire over the 3 meter length of the polyimide tube. We also appreciated that it would be desirable to devise a mechanism for locking the polyimide tubing to the guide wire.

65. In the embodiment of our invention disclosed in Exhibit 1, the Chronoflex embolic filter is attached to a long polyimide tube, which has a lumen that is sized to permit rotation and translation of the filter element (*i.e.*, the polyimide tube support and the Chronoflex filter mounted thereon) on the guidewire.

66. In our efforts to reduce to practice this embodiment of our invention, prior to March 5, 1998, we realized that due to the long length of the polyimide tube, which must bend in order to conform to the path followed by the filter element in the arteries, there was friction between the 0.014″ guidewire and the lumen of the polyimide tube, which was 0.145″.

67. In our efforts to reduce our invention to practice, prior to March 5, 1998 we also appreciated that there was friction between the exterior of the long polyimide tube and the lumen of the retrieval catheter, which significantly increased the force required to withdraw the embolic filter into the withdrawal catheter, by pulling on the polyimide tube.

68. In order to solve these problems, prior to March 5, 1998, we conceived of a custom stepped guidewire configuration, having a proximal portion with a diameter smaller than conventional 0.014″ guidewire, and a distal tip portion with a diameter larger than the 0.0145″ lumen diameter of the polyimide tubing.

69. In a conference call design review meeting prior to March 5, 1998, Chas Taylor referred to a solution to this problem by using a custom guidewire, having a thinner proximal portion on which the filter element polyimide tube support is mounted. He referred to using a stepped guidewire having a proximal diameter of 0.012″ and a distal end diameter of 0.018″.

70. Our conception is corroborated by an email describing the meeting, having a date before March 5, 1998, which was attended by inventors Chas Taylor, Padraig Maher, David Vale and Eamon Brady, and also by John O'Shaughnessy. This email was sent before March 5, 1998, to Susan Eighan and Mairsil Claffey, and is attached as Exhibit 3.

71. Prior to March 5, 1998, we appreciated that our invention of using a stepped guidewire, having a distal end portion with a diameter greater than the inner diameter of the polyimide tube (0.0145″) would serve as a distal stop, which limits distal translation of the filter on the guidewire. The stepped guidewire has a distal end diameter larger than the 0.0145″ inner diameter of the polyimide filter support.

72. Prior to March 5, 1998, we considered that the smaller diameter proximal section of this stepped guidewire configuration would facilitate rotation and distal translation of the guidewire relative to the filter element.

73. Prior to March 5, 1998, we considered that the larger diameter distal tip of this stepped guidewire configuration would act as a stop for the polyimide tube support of the filter element, preventing the guidewire from being withdrawn through the polyimide tube.

74. Prior to March 5, 1998, we considered that this two-diameter guidewire configuration would permit the transfer of some of the withdrawal load from the polyimide tube to the guidewire, by retracting the guidewire in a proximal direction to cause the thicker distal guidewire tip portion to abut against the

polyimide tube support of the filter element, thus reducing the load on the filter element during withdrawal.

75. Prior to March 5, 1998, we also appreciated that this stepped guidewire configuration providing a distal stop would permit the guidewire to be used to withdraw the expanded filter into a retrieval catheter, by retracting the thicker distal stop portion of the guidewire to abut the end of the polyimide tube filter support, and by pulling the guide wire proximally to retract the filter element into a retrieval catheter.

76. We thus appreciated that retracting the guide wire in a proximal direction causes the distal stop to abut against the filter element, when the guidewire is pulled to retract the filter element into a retrieval catheter. Paul Gilson disclosed this advantage at a management meeting, prior to March 5, 1998, describing it as a "Fail Safe" filter interface. This meeting was attended by John O'Shaughnessy, Kate Bingham (Director of MedNova) and David Gibbons (Chairman of MedNova). Exhibit 99 is a copy of a slide from that presentation describing the guidewire as having a stepped 0.013"/0.016" design with a "Fail Safe" filter interface. The same slide was used by Paul Gilson in a presentation to Dr. Gary Roubin prior to March 5, 1998, at a meeting at Dromoland Castle in Ireland. Exhibit 104 is a copy of an entry in Paul Gilson's scheduler dated prior to March 5, 1998, referring to the meeting at Dromoland Castle with Dr. Roubin.

77. Prior to March 5, 1998, we and our coworkers at MedNova constructed an embodiment of a prototype filter device and system which was designated as the "NeuroShield Mark 1" embolic filter protection system. A true and accurate photograph of the NeuroShield Mark 1 embolic filter protection system on a support is attached as Exhibit 90.

78. This prototype NeuroShield Mark 1 filter system corroborates our conception of the following limitations of Count 2, as shown in the following table:

NeuroShield Mark 1 Prototype (Exhibit 90)
The filter system is used in the method disclosed in Irish Application No. 97 0789, where a representative filter is shown, *e.g.*, in Fig. 18. The balloon filter shown in Exhibit 90 is mounted on a polyimide tube support having an inner diameter of 0.0145″, and the filter may be disposed for translation on a guidewire proximal of the distal stop. The polyimide tube support would prevent the filter from translating distal of the guidewire stop. The balloon filter shown in Exhibit 90 has a number of self-expanding Nitinol shape-memory struts supporting the expanded filter sac, which is attached to the Nitinol support. The balloon filter is shown in Exhibit 90 in its deployed configuration, as described in Irish Application No. 97 0789, as it would engage a wall of the vessel and filter emboli out of blood flowing through a vessel in which the filter is deployed. Treatment devices such as a balloon catheter or a stent balloon catheter are treatment devices which would be inserted into a vessel to treat a portion of the vessel, and in the device shown in Exhibit 90, they are advanced along a guidewire to a position proximal of the filter element, as described in Irish Application No. 97 0789. The inner lumen of the polyimide tube filter support shown in Exhibit 90 has a diameter of 0.0145″, and the proximal region of a guidewire for use therewith used with the filter support has an outer diameter of 0.013″. Exhibit 90 thus confirms that rotation or distal translation of the guide wire relative to the filter element does not displace the filter element. As shown in Exhibit 90, a guidewire can be translated through the filter polyimide tube support without displacing the filter element. The guidewire can also be rotated in the filter polyimide tube support without displacing the filter element. In order to retrieve the filter, a guidewire is retracted to cause the distal stop to abut against the filter element. The prototype filter system includes a wire lock device, which is used to hold the guidewire in place while the retrieval catheter is pushed over the filter, with the distal stop abutting against the filter element.

III. DILIGENT EFFORTS TO REDUCE OUR INVENTION TO PRACTICE

79. From a time prior to March 5, 1998 until the filing of Irish Patent Application No. 98 0267 on April 8, 1998, we and other members of MedNova were engaged in continuous, diligent efforts to produce and test a practically useful embodiment of our embolic filter inventions defined by Count 1 and Count 2.

80. During the period from late February 1998 until April 8, 1998, we and other MedNova employees working at our direction were intensely involved in preparing for tests of our filter system and methods in New York, which were conducted at Montefiore Hospital in the Bronx on March 14, 1998, and again on April 5, 1998.

81. Our preparation for these tests in New York commenced in January 1998, when Chas Taylor contacted Dr. Takao Ohki to arrange for the use of his laboratory, and also arranged for Dr. Gary Roubin to conduct the test procedures. Exhibit 105 is a copy of an entry in Paul Gilson's scheduler prior to March 5, 1998, referring to dinner in New York with Drs. Roubin and Ohki and Chas Taylor. Dr. Roubin's wife (Peta) also attended.

82. During this period, Paul Gilson and Chas Taylor twice traveled to New York, to observe tests of prototype "NeuroShield" embolic filters in Dr. Ohki's laboratory at Montefiore Hospital, in the Bronx, on March 14, 1998 and on April 5, 1998. Attached as Exhibits 92, 93, 94, and 95, are the expense reports for Chas Taylor and Paul Gilson in connection with these two trips to New York. The tests were conducted by Dr. Gary Roubin, an interventional cardiologist, and are described in Dr. Roubin's Declaration. Fluoroscopic images of the test procedures were recorded and are included in Exhibit 91.

83. The following description of the tests performed by Dr. Roubin is based on the observations of Paul Gilson and Chas Taylor.

84. On March 14, 1998, Dr. Roubin tested a "NeuroShield" embolic filter at Montefiore Hospital in the Bronx, New York, USA. Exhibit 31 is a facsimile from Chas Taylor on March 11, 1998, describing the meeting. Exhibit 106 is a copy of an entry in Paul Gilson's scheduler indicating that March 14, 1998, was set aside for the tests.

85. The March 14, 1998, tests used a prototype "Mark 1" NeuroShield filter device and system, substantially as shown in Exhibit 90.

86. Fluoroscopic and angioscopic images recorded during the March 14, 1998 test were recorded, including the images attached as Exhibit 91.

87. Paul Gilson and Chas Taylor attended the March 14, 1998 test.

88. The March 14, 1998 test was performed using a model which employed a simulated artery containing a surgically explanted human carotid artery plaque, which was sutured into a PTFE surgical graft to simulate an artery. Distal vasculature was represented by a 5 mm PTFE graft sutured to the system. The whole assembly was mounted in a water bath that was not temperature controlled, with access to the lesion by way of Teflon catheters. Endoscopic and fluoroscopic imaging was recorded. A filter was set up distally to capture any material not retained by the MedNova filter. Blood flow through the simulated artery and the embolic filter was simulated using a saline gravity flow whereby saline solution flowed through the simulated artery. This test procedure is correctly described in a contemporaneous memorandum prepared by Paul Gilson (Exhibit 37).

89. The "NeuroShield" device which Dr. Roubin tested on March 14, 1998, utilized a stepped guidewire having a distal stop. The distal end of the guidewire had a diameter (*i.e.*, 0.016″) that was greater than the diameter of the polyimide tube filter support (*i.e.*, 0.0145″), and provided a stop which prevented distal translation of the filter element beyond the guidewire distal stop. The proximal guidewire shaft had a diameter (*i.e.*, 0.013″) that was

smaller than the lumen of the polyimide tube supporting the filter. It was therefore possible to rotate and distally translate the guidewire relative to the filter and its polyimide support.

90. In the "NeuroShield" device which Dr. Roubin tested on March 14, 1998, the balloon filter element had a filter sac attached to a Nitinol framework having a number of self-expanding struts, and the Nitinol framework was attached to a polyimide filter support.

91. In the "NeuroShield" device, which Dr. Roubin tested on March 14, 1998, the stepped guidewire was backloaded through the polyimide tube filter support. The distal end of the stepped guidewire would not pass through the polyimide tube filter support, and provided a distal stop on the guidewire. The filter element was thus disposed for translation on the guidewire proximal of the distal stop.

92. A representation of the prototype embolic filter substantially the same as that used by Dr. Roubin in the March 14, 1998 tests, including a filter sac supported by self-expanding Nitinol struts, the polyimide tube filter support, and the stepped guidewire, is shown in Exhibit 90.

93. The balloon filter sac structure of the filter that was used in the March 14, 1998 tests is also schematically shown in Exhibit 65. Instructions for prepping and using the device were given to Dr. Roubin in connection with the March 14, 1998 tests.

94. The expanded filter used in the March 14, 1998 tests is shown disposed on the guidewire in Exhibit 88. In order to transluminally insert the filter into the vessel, it was necessary to compress the filter using a loading device, and to insert the compressed filter and guidewire into a delivery catheter.

95. During the March 14, 1998 test, the guidewire and compressed filter element were first inserted into a delivery catheter.

96. Dr. Roubin inserted the delivery catheter, including the guidewire and compressed filter, into the model.

97. Dr. Roubin then successfully crossed the lesion narrowing the vessel with the guidewire. During this procedure, the guidewire was maneuvered through the lesion, and the guidewire rotated and translated distally with respect to the filter element, without displacing it.

98. The delivery catheter was used to transluminally insert the filter and guidewire to a position distal of the plaque in the vessel by advancing the filter and delivery catheter independently of the guidewire.

99. The filter was then deployed so that the struts and filter sac thereof expanded to engage a wall of the vessel.

100. Dr. Roubin then advanced a balloon dilation catheter over the guidewire to a position proximal to the location of the deployed filter, and expanded the balloon to dilate the plaque.

101. Embolic material was released when the plaque was disrupted by the balloon.

102. Dr. Roubin then retracted the balloon catheter, and advanced a stent over the guidewire to the target deployment site.

103. Dr. Roubin then deployed the stent at the lesion, and the expansion of the stent released embolic material from the plaque. Dr. Roubin then removed the stent delivery system from the vessel.

104. Dr. Roubin subsequently advanced the retrieval catheter over the guidewire and crossed the stented region and placed the distal tip of the stent delivery catheter proximal of the expanded filter.

105. Dr. Roubin retracted the guide wire in a proximal direction to cause the distal stop of the guidewire to abut against the polyimide filter support. He advanced the retrieval catheter relative to the filter to collapse the filter and withdraw it into the retrieval catheter. He then removed the retrieval catheter containing the filter from the vessel.

106. Dr. Roubin then removed the filter from the retrieval catheter. The filter was then cut open. A number of large embolic particles were visible in the opened filter.

107. These tests confirmed that the filter filtered emboli out of the saline solution.

108. During the simulated treatment procedure, the guidewire and filter delivery catheter successfully crossed the lesion, the filter was delivered, the filter was deployed, the filter captured embolic material and the filter was retrieved.

109. During the simulated treatment procedure, the guidewire was rotated and distally translated relative to the filter element, both before deployment and after expanding the filter in the vessel. Rotation and distal translation of the guidewire relative to the filter element did not displace the expanded filter element deployed in the vessel. Rotation and distal translation of the guidewire prior to deployment did not displace the compressed filter element in the delivery catheter.

110. During the simulated treatment procedure rotation or distal translation of the guide wire was possible, although perfect manipulation of the guidewire at times was difficult due to some friction between the guidewire and the polyimide support of the filter.

111. The filter element deployed in the vessel so that the struts and filter sac expanded to engage a wall of the simulated artery.

112. The March 14, 1998 tests and results are accurately described in Paul Gilson's March 18, 1998 memorandum, attached as Exhibit 37.

113. After the March 14, 1998 test, we designed a version of the "NeuroShield" embolic filter which provided a filter element intended to provide better rotation and translation movement of the guidewire.

114. On March 24, 1998, Paul Gilson disclosed the version of the "NeuroShield" embolic filter to Dr. Roubin in a facsimile attached as Exhibit 60, page 3.

115. In his March 24, 1998 facsimile, Paul Gilson described MedNova's changes to the first version of the "NeuroShield" embolic filter, which included mounting the filter on a short polyimide tube support to which the Nitinol filter support was bonded. This configuration allowed the filter assembly to move between pre-determined stops on the guide wire, and thus the wire was free to torque and to have limited movement longitudinally (Exhibit 60, page 3).

116. In his March 24, 1998 facsimile, Paul Gilson also stated that MedNova would be ready by April 3rd or 4th, 1998, to evaluate the second version of the "NeuroShield" embolic filter (Exhibit 60, page 1). It was a major undertaking to modify the filter element, and to produce additional prototype devices, for the second test of the filter system, within three weeks. Exhibit 107 is a copy of an entry in Paul Gilson's scheduler dated Wednesday, March 25, 1998, noting to contact Dr. Roubin to discuss the design changes to the device. Exhibit 108 is a copy of an entry in Paul Gilson's scheduler dated March 26, 1998, noting to arrange the availability of Dr. Ohki's laboratory for the second trial. Exhibit 109 is copies of entries in Paul Gilson's scheduler dated April 4 and 5, 1998, containing notes for the second trial conducted April 5, 1998.

117. On April 5, 1998, Dr. Roubin tested the subsequent version of a "NeuroShield" embolic filter at Montefiore Hospital in the Bronx, New York, USA. (Exhibits 79, 81).

118. Paul Gilson and Chas Taylor attended the April 5, 1998 test.

119. The April 5, 1998 test was performed using the test procedures described above.

120. The "NeuroShield" device tested on April 5, 1998 utilized a stepped (0.013″/0.016″) guidewire having an improved distal stop. For this test, because the polyimide was of short length, there was a need to enhance the contact area between the distal stop (step on the wire) and the distal end of the

polyimide tube. This was done by bonding a short length of stainless steel tube just proximal of the distal step on the wire. This was a temporary measure until the modified stepped guidewire could be provided by Lake Region.

121. In the revised "NeuroShield" device, the stepped guidewire was preloaded through a balloon filter element having a filter sac which was affixed to a Nitinol support having a number of self-expanding struts.

122. In the revised "NeuroShield" device, the Nitinol framework was attached to a short (about 40 mm) polyimide tube support disposed proximal of the distal stop, between the distal stop and a proximal stop, as shown in Exhibit 60, page 3, and Exhibits 81 and 88). Because the short polyimide tube had a lumen with an inner diameter smaller than the diameter of the distal stop of the guidewire, the distal end of the guidewire would not pass through the polyimide tube and provided a distal stop. The filter element was disposed for translation and rotation on the stepped guidewire proximal of the distal stop.

123. The short polyimide tube (about 40 mm) floated on the guidewire between the distal stop and the proximal stop. The filter element was thus capable of rotation and distal translation with respect to the guidewire in a manner equivalent to the earlier version of the device.

124. The modified NeuroShield filter and guidewire which Dr. Roubin tested on April 5, 1998, are accurately described in the drawing prepared by David Vale on or before April 8, 1998, contained in Exhibit 81.

125. During the April 5, 1998 test, the guidewire and compressed filter element were inserted into a delivery catheter.

126. Dr. Roubin inserted the delivery catheter, including the guidewire and compressed filter, into the model.

127. Dr. Roubin successfully crossed the lesion narrowing the vessel with the delivery catheter, to a position distal of the lesion.

128. Dr. Roubin deployed the filter element so that the struts and filter sac thereof expanded to engage a wall of the vessel.

129. Dr. Roubin advanced a balloon dilation catheter (*i.e.*, a treatment device) over the guidewire to a position proximal to the location of the deployed filter, and expanded the balloon to dilate the plaque (*i.e.*, treat a portion of the vessel) so that the lesion was disrupted.

130. Dr. Roubin retracted the balloon catheter, and advanced a stent delivery catheter over the guidewire to the target deployment site, where the stent was deployed.

131. During the above steps, embolic material was dislodged from the plaque, and was successfully captured in the filter.

132. Dr. Roubin advanced a retrieval catheter over the guidewire to a position distal of the stent and proximal of the expanded filter.

133. Dr. Roubin retracted the guide wire in a proximal direction to cause the distal stop of the guidewire to abut against the filter support.

134. Dr. Roubin withdrew the filter into the pod of the retrieval catheter, and removed the retrieval catheter containing the filter from the simulated artery.

135. Dr. Roubin removed the filter from the retrieval catheter and it was cut open. A number of large embolic particles were visible in the opened filter.

136. The filter filtered emboli out of the saline solution flowing through the simulated artery. The filter system successfully crossed the lesion, the filter was successfully deployed, the filter captured embolic material and it was successfully retrieved.

137. During the tests on April 5, 1998, rotation and distal translation of the guide wire relative to the deployed filter was maintained and improved in comparison with the "NeuroShield" device which Dr. Roubin tested on March 14, 1998.

138. Based on the two tests conducted by Dr. Roubin, we continued our efforts to modify, improve, and perfect the filter system from April 5, 1998 until April 8, 1998, when Irish Application No. 98 0267 was filed.

139. Our continuous efforts during the period from prior to March 5, 1998 until April 8, 1998, to test the methods defined by Count 1 and Count 2, were directed at improving the parts of the filter element, as well as components such as the delivery catheter used to transluminally insert the guidewire and filter element into a vessel, and to perform the methods.

140. These efforts are described in numerous documents, including detailed filter development Project Team Meeting Reviews, summarizing the activities of team members directed toward an actual reduction to practice in the preceding and following week.

141. The Project Team Meeting Reviews and other documents demonstrate that we and our colleagues were working intensely and continuously to produce a filter and system that would be shown to be practically useful in the tests conducted by Dr. Roubin, during the period from a date just prior to March 5, 1998, until April 8, 1998. These Project Team Meeting Reviews and other documents are attached as the following exhibits:

February 25, 1998:	Exhibit 8
March 5, 1998:	Exhibit 22
March 11, 1998:	Exhibit 33
March 18, 1998:	Exhibit 48
March 24, 1998:	Exhibit 38
April 1, 1998:	Exhibit 74
April 2, 1998:	Exhibit 77
April 6, 1998:	Exhibit 83

142. During the period from February 1998 until April 8, 1998, Paul Gilson arranged in February 1998 for Dr. Roubin to conduct the tests; coordinated the tests in New York on March 14, 1998 and April 5, 1998; traveled to New York to attend these tests; evaluated the results of the tests; modified and

improved the filter to improve movement of the guidewire relative to the filter; and worked with Dr. Roubin in evaluating the design changes proposed by the inventors.

143. During the period from February 1998 until April 8, 1998, Susan Eighan, who was a Manufacturing Engineer, worked to make final packs for the tests conducted by Dr. Roubin (Exh. 22, 33), as well as working on the core removal process for making the filter balloon sacs (Exh. 33), making and improving Nitinol supports (Exh. 33, 77, 83), building filter samples (Exh. 48); and manufacturing the filter assembly (Exh. 38, page 2).

144. During the period from February 1998 until April 8, 1998, Steven Horan, who was a Research and Development Engineer, worked principally on the balloon filter sac, including narrowing the balloon wall thickness distribution, updating the dip and core assembly procedures used to make the balloons, and conducting tests of the balloons (Exh. 8, 22); building 36 balloons for the tests conducted by Dr. Roubin (Exh. 22, 33); analyzing balloon data and evaluating balloon strengths, ordering cores for making the balloons, and dipping balloons for UV trials (Exh. 33, 48); prototyping alternative balloons for the April 5, 1998 trials in New York (Exh. 38, page 1), including tapered filter or stepped filter or grooved filter designs to improve filter performance in undersized vessels (Exh. 74); making and testing about 35 prototype balloons for the April 5, 1998 trials (Exh. 77); and evaluating and testing a series of filter geometries and sizes (Exh. 83).

145. During the period from February 1998 until April 8, 1998, Padraig Maher, who was a Research and Development Engineer, tested Nitinol supports, provided samples of the Nitinol supports to a laser machining company, and tested the loading force required to load the filter element into a delivery catheter and tested the maneuverability of the delivery catheter (Exh. 8, 22, 33); defined a balloon wrap method (Exh. 22, 33); worked with Chas Taylor

to increase the number of distal holes in the balloon filter (Exh. 38, page 2); ordered thicker polyimide tube for the filter support, and built prototypes using the new polyimide tube (Exh. 74, 77, 83); increased the size of the proximal filter holes (Exh. 83); and built "olives" to improve the transition from the delivery catheter to the filter element (Exh. 74, 77, 83).

146. During the period from February 1998 until April 8, 1998, Keith Ryan, a technician, worked with David Vale on the delivery catheter pod used to transluminally insert the filter and guidewire past the plaque, and tested pod tensile strengths (Exh. 8); worked on the rig used to test the PTFE pod attachment (Exh. 22); built 10 loading mechanisms for use in the trials, which were used to load the filter element into the delivery catheter (Exh. 33); tested additional loading mechanisms (Exh. 77, 83); and worked on the wall thickness and diameter of the Teflon pod of the delivery catheter (Exh. 74, 77); and modified the loading mechanism transition of the delivery catheter (Exh. 77, 83).

147. During the period from February 1998 until April 8, 1998, David Vale, who was Senior Research and Development Engineer, worked on the retrieval catheter specifications (Exh. 22, 33); worked on the delivery catheter (Exh. 38, page 2); modified the filter element design, and worked on the stops for the filter, as well as materials and processes for the stops on the guidewire (Exh. 74, 77); designed, built and evaluated a filter design with floating distal bonds (Exh. 83); and worked on improving the smoothness of guidewire transitions and improving guidewire stiffness (Exh. 83, page 2).

148. Our activities, including the activities of other MedNova employees, in the period from February 25, 1998 until April 8, 1998 are described in more detail as follows.

149. Our activities are described in numerous documents, including detailed filter development Project Team Meeting Reviews, summarizing the activities of

each team member directed toward an actual reduction to practice of the embolic filter protection system and methods in the preceding and following week. The Project Team Meeting Reviews are documents that were regularly prepared in the course of business by Eamon Brady and/or Chas Taylor, shortly after the team's meetings on the dates indicated in the reports. The reports were regularly distributed to the team members working on the embolic filter project, as well as to John O'Shaughnessy and to Mairsil Claffey, and are maintained by Eamon Brady in MedNova's files relating to the project. They accurately describe MedNova's efforts to produce and improve the embolic filter system during the period from late February to April 8, 1998.

150. To the extent that we may not have personal knowledge of each of the documents referred to herein, on information and belief, we believe that the orders, invoices, specifications, reports, emails, memoranda and other documents attached as exhibits are true copies of contemporaneous documents made and kept by MedNova in the regular course of business, and that they accurately reflect the activities of the inventors and other MedNova employees on the dates indicated in the documents.

151. Exhibit 8 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on February 25, 1998.

152. The attendees at the February 25, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Mary Gallagher ("MG"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady; and were sent to Marsail Claffey ("MC"), Chas Taylor ("CT"), and Paul Gilson ("PG").

153. The responsibilities of MedNova's research team working on the embolic filter development project in February and March 1998 are correctly stated in Exhibit 8.

154. Keith Ryan was generally responsible for PTFE shrink development work, which was necessary to make the delivery catheter used to transluminally insert the filter element into a vessel.

155. Shivaun O'Rourke was generally responsible for activities in support of test development and evaluation of prototype devices, including embolic filter prototypes.

156. Susan Eighan was generally responsible for catheter manufacturing line setup, and for Nitinol forming and balloon bond process development used in producing the embolic filter element assemblies.

157. Padraig Maher was generally responsible for core punching, core assembly and specifications for the cores used to produce the filter sac used in the embolic filter element.

158. Jon Hager was generally responsible for vendor approval, receiving goods system and documentation. He was also responsible for DMR (device master record) development, which defines how the device is built.

159. David Vale was generally responsible for producing the retrieval catheter used to retrieve the filter element from the artery after performance of carotid artery angioplasty procedures, for development of the loading mechanism for compressing the expanded balloon filter and loading it into the delivery catheter, and for packaging.

160. Steven Horan was generally responsible for filter sac ("balloon") development.

161. Chas Taylor was generally responsible for labeling and instructions for use.

162. In the week prior to February 25, 1998, Keith Ryan tested pod tensile strengths, for the pod used to deliver the filter; and Shivaun O'Rourke updated the pod shrink validation protocol.

163. In the week prior to February 25, 1998, Susan Eighan worked on sterilization procedures for the filter element ("balloon bond") and started work on the sterility of the delivery catheter required for transluminal insertion of the guidewire and filter element in the vessel.

164. In the week prior to February 25, 1998, Padraig Maher tested the Nitinol framework used to expand the filter element, and sent samples to the laser company that laser machined the Nitinol frame.

165. In the week prior to February 25, 1998, Jon Hager inspected dipped balloons used as the filter sac in the self-expanding filter.

166. In the week prior to February 25, 1998, David Vale worked in defining the pod shrink process used in producing the filter delivery catheter, and initiated the construction of the packaging.

167. In the week prior to February 25, 1998, Steven Horan analysed Taguchi test results, which related to optimizing the process for making the filter sacs, and updated the dip and core assembly procedures used to produce the filter sac balloons. Steven Horan on February 25, 1998, prepared document no. MP97 009, revision 5 (Exhibit 9) which describes the method used to assemble the soluble core assembly that is used to make the Chronoflex balloon.

168. On February 25, 1998, David Vale prepared document no. TP97022, (Exhibit 10), which describes the method for determining and quantifying the integrity of the retrieval catheter tip under a compressive load. A retrieval catheter is used to collapse the self-expanding embolic filter after the procedure is completed.

169. Invoices and other records made and maintained by MedNova in the regular course of business show that in the week following February 25, 1998,

MedNova's vendors supplied materials that were used in preparing prototype filter systems, and MedNova ordered additional supplies related to producing the prototype systems. These documents demonstrate that MedNova was engaged in a continuous effort to obtain supplies used to produce and test prototype embolic filter devices used in the methods according to Counts 1 and 2 during this period.

170. On February 26, 1998, MedNova received a shipment of Monel wire from Fairbanks Wire Co. (Exhibit 11), which was required to produce the loading funnel and delivery catheter pod.

171. On February 26, 1998, Boston Scientific shipped vials of Contour™ particles to Chas Taylor (Exhibit 97), which were required to test embolic material capture. Exhibit 101 is a photograph of five of the bottles of Contour™ particles received from Boston Scientific.

172. On February 26, 1998, Payne Plastics shipped machined Perspex rod to MedNova (Exhibit 12), which was required to produce the loading funnel. This shipment was received on March 4, 1998.

173. On February 27, 1998, Dawnlough, Ltd. shipped Perspex rod to MedNova (Exhibit 13), which was received on March 6, 1998. This rod was required to produce the loading funnel.

174. On February 27, 1998, Euroflex shipped laser cut parts from Nitinol slit tubing, according to drawing CE 97 003, Rev. 04 (Exhibit 14). These parts were required to produce Nitinol supports for the embolic filter element.

175. On February 27, 1998, MedNova ordered closed coil stainless steel spring according to specification CD 97 002 from Ashfield Springs (Exhibit 15). These springs were required to produce the delivery catheter, and were shipped March 18, 1998 (Exhibit 20).

176. On February 27, 1998, MedNova issued a purchase order to Adam Spence for a spline press tool (Exhibit 16), which was used to produce the retrieval catheter distal tip.

177. On February 28, 1998, Dawnlough, Ltd. shipped Nitinol formers to MedNova (Exhibit 96), which were required to produce the self-expanding Nitinol struts for the embolic filter element. The Nitinol formers were received on March 11, 1998.

178. On March 2, 1998, Medical Profiles Inc. shipped hemostasis Y-connectors to MedNova (Exhibit 18), which were required to produce the delivery catheters.

179. On March 3, 1998, MedNova ordered from National Heat Treatment Centre, UCD, the annealing of Monel 400 wire (Exhibit 21). This wire was required to produce the delivery catheter, pod and loading funnel. The heat-treated wire was shipped on March 30, 1998 (Exhibit 17).

180. Exhibit 22 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 5, 1998.

181. The attendees at the March 5, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady; and sent to Mairsil Claffey ("MC"), Chas Taylor ("CT"), and Paul Gilson ("PG").

182. The general responsibilities of MedNova's research team members working on the embolic filter development project in March 1998 are correctly stated in Exhibit 22.

183. In the week prior to March 5, 1998, Keith Ryan wrote a pouch seal procedure for packaging the filter.

184. In the week prior to March 5, 1998, Shivaun O'Rourke drafted a pouch seal protocol, and prepared a validation protocol for the Touhy Borst connector used in the delivery catheter.

185. In the week prior to March 5, 1998, Susan Eighan worked on evaluating sterility of the filter element to the balloon bond post-sterilization.

186. In the week prior to March 5, 1998, Padraig Maher conducted short length and full length loading force measurement testing on the filter and loading funnel, which related to measuring the ease of filter loading. He also conducted full length loading force testing on the filter system, which related to the forces experienced by the end user.

187. In the week prior to March 5, 1998, Steven Horan worked on the dipping process for manufacturing expandable filter sac balloons, narrowing the balloon wall thickness distribution, and completed a trial with vacuum for removal of bubbles, which was necessary to improve process control.

188. On or about March 2, 1998, a protocol was prepared for a maneuverability test fixture, which was a template which simulates the path likely to be taken by a guide catheter in reaching the site of a carotid intervention. (Exhibit 23). This model was designed to test the delivery catheter used to transluminally insert the filter element into a vessel, and represented a tortuous path of insertion. The model is used to estimate the force required to insert or withdraw catheters in vessels. On or about March 2, 1998, a test protocol TP97 017 was drafted describing this procedure (Exhibit 24). The February 25, 1998, Project Team Meeting Review indicates that on of the next week's key goals for Padraig Maher was full length loading force testing and maneuverability test rig design. (Exhibit 8). Padraig Maher was familiar with the preparation of Exhibits 23 and 24.

189. Shivaun O'Rourke drafted a protocol for calibration of flow meters used to measure the flow rate in a test rig simulating the flow of blood in a simulated

carotid artery (Exhibit 25 dated March 2, 1998). This device was used to test embolic capture ability, and is illustrated in a drawing prepared by Shivaun O'Rourke or John Hager on March 3, 1998 (Exhibit 26).

190. Keith Ryan prepared a screening validation procedure for the process used to shrink PTFE tubing onto a copper mandrel for preparing the delivery pod and loading funnel, and a test method for measuring PTFE integrity and its bond strength to the loading funnel (Exhibit 19 dated March 4, 1998).

191. Padraig Maher prepared a drawing of a test rig used to test the force required to retrieve the embolic protection filter into the pod of the retrieval catheter (Exhibit 26 dated March 4, 1998).

192. The March 5, 1998 Project Team Meeting Review (Exhibit 22) confirms that at this time we were preparing for the tests of the embolic filter protection system in New York.

193. Exhibit 22 indicates that a key goal for Steven Horan in the next week was building 10 balloons for filters to be used in the tests, and that a key goal for Susan Eighan was to build 10 final packs for the trials.

194. Exhibit 22 describes the next week's key goals for team members, in the week following March 5, 1998, as follows.

195. Keith Ryan's key goals included defining a pouch seal process window, which related to packaging.

196. Shivaun O'Rourke's key goals included approving a pod shrink protocol, which related to testing the manufacturing outputs from the pod shrink test protocol, and approving the pouch seal protocol.

197. Susan Eighan's key goals included building 10 final packs for the tests of use of the embolic protection system, evaluating sterility of the filter element to the balloon bond post-sterilization, and finalizing the core removal process, which was used in making the balloon filter membrane sacs.

198. Padraig Maher's key goals included fatigue and tensile tests of the Nitinol frame, and defining a sac balloon wrap method for loading.

199. David Vale's key goals included updating the retrieval catheter specification, ordering retrieval catheter bench test parts, and building sterility pieces used for post-sterile testing of retrieval catheter.

200. Steven Horan's key goals included building 10 balloons for the Ohki trials, and building balloons for post-sterility testing.

201. On March 6, 1998, Shivaun O'Rourke reported on the status of process screening validations for the embolic filter protection device system, including Nitinol forming and balloon bonding screening for the filter; delivery catheter pod shrinkage screening, and preparation of the delivery catheter loading pod by shrinkage of PTFE onto Monel wire; and the Touhy Borst to delivery catheter shaft bonding. (Exhibit 39).

202. David Vale prepared a drawing (Exhibit 28 dated March 6, 1998) with specifications for the retrieval catheter assembly (SA97 006 Rev. 2) used to retrieve the filter element from a vessel after treatment of the vessel. A copy of this specification was sent to Adam Spence with an order for retrieval catheters made according to the revised specification on March 6, 1998. (Exhibit 29).

203. Keith Ryan prepared a drawing (Exhibit 30 dated March 9, 1998) and specification (SA98 006 Rev 01) for the delivery catheter used for transluminally inserting the filter element into a vessel. This drawing illustrates the Touhy Borst connector, catheter spring shaft having a shrunk PTFE cover, and distal PTFE pod that is used to hold the compressed balloon filter assembly during transluminal insertion.

204. Keith Ryan prepared a specification (SA98 005 revision 01) for the loading mechanism subassembly, which is used to compress and load the balloon filter into the delivery catheter. (Exhibit 34 dated March 10, 1998).

205. On March 11, 1998, Chas Taylor sent a facsimile to Paul Gilson and Dr. Gary Roubin, making final arrangements for meeting in New York at Montefiore Hospital to conduct tests of the embolic filter system. (Exhibit 31).

206. Steven Horan prepared a drawing (Exhibit 32 dated March 9, 1998) and specification (CC98 001 Rev. 01) of the soluble core used to make the balloon used as a filter sac in the embolic filter element.

207. Exhibit 33 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 11, 1998.

208. The attendees at the March 11, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); David Vale ("DV"); Jon Hager ("JH"); Susan Eighan ("SE"); Mairsil Claffey ("MC"); Paul Gilson ("PG") and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady.

209. The responsibilities of MedNova's research team working on the embolic filter development project in March 1998 are correctly stated in Exhibit 33.

210. In the week prior to March 11, 1998, Keith Ryan built 10 loading mechanisms for the trials in New York.

211. In the week prior to March 11, 1998, Shivaun O'Rourke approved the pouch seal protocol, relating to packaging.

212. In the week prior to March 11, 1998, Susan Eighan built 10 final packs for the trials in New York, and completed the delivery catheter sterility/bio build.

213. In the week prior to March 11, 1998, Padraig Maher fatigued tested Nitinol struts used in the balloon filters, and analyzed loading force data relating to filter assembly loading.

214. In the week prior to March 11, 1998, David Vale updated the retrieval catheter specification (Exhibit 28), ordered retrieval catheter bench test parts (Exhibit 33), and had built retrieval catheters for post-sterility testing.

215. In the week prior to March 11, 1998, Steven Horan built 36 balloons for the tests in New York.

216. Exhibit 33 describes the next week's key goals for team members for the week following March 11, 1998, as follows.

217. Keith Ryan's key goals for the week included defining a pouch seal process window, and pod screening of the overlap joint, which related to the delivery catheter.

218. Shivaun O'Rourke's key goals for the week included approving the pod shrink protocol and updating the pod shrink validation, both of which related to the delivery catheter.

219. Susan Eighan's key goals for the week included evaluating sterility of the filter element to the balloon bond post sterilization, resolving Teflon shrink process issues, finalizing the core removal process used to produce the filter balloon sacs, and putting process controls in place to correct a Nitinol cracking issue.

220. Padraig Maher's key goals included writing up Nitinol test results, and evaluating deployment and retrieval force encountered in inserting and removing the embolic filter.

221. David Vale's key goals included completing pod engineering studies, which related to the delivery catheter.

222. Steven Horan's key goals related to development of the balloon filter sac, and related to process development of the filter sac including analyzing balloon data, evaluating balloon strengths, dipping balloons for UV adhesive bonding trials, and ordering cores for making the balloon filters.

223. On March 12, 1998, MedNova ordered Y-connectors from Qosina (Exhibit 57), which were required for the delivery catheters. The purchase order was received by Qosina March 13, 1998 (Exhibit 35). These parts were shipped on March 16, 1998 (Exhibit 36), and were received on March 20, 1998 (Exhibit 36).

224. On March 14, 1998, Dr. Gary Roubin performed a test of MedNova embolic protection systems. This test was attended by Paul Gilson and Chas Taylor. Exhibit 37 is a report of the *in vitro* plaque filtration test prepared by Paul Gilson.

225. In the week following the March 14, 1998 trial in New York, Paul Gilson returned to Ireland and the MedNova research team worked to modify the embolic filter protection system. These proposed changes were discussed at a meeting on March 23, 1998, attended by Paul Gilson, Padraig Maher; Steven Horan, David Vale, Susan Eighan, Mairsil Claffey, Chas Taylor and Eamon Brady.

226. Eamon Brady prepared a summary of the Design Review Meeting and distributed the Design Review Minutes to the participants on March 24, 1998 (Exhibit 38).

227. Among other improvements to the embolic protection filter system, we discussed modifying the balloon design to improve the sizing performance of the filter in vessels of smaller size, and improving wire movement. (Exhibit 38).

228. Steven Horan was assigned responsibility for prototyping a series of alternative balloon designs, intended to improve sizing performance in vessels of smaller size. (Exhibit 38, page 2).

229. We also decided to increase the delivery catheter shaft outer diameter to accommodate the internal pusher for deploying the filter element. (Exhibit 38).

230. We also decided to change the filter element by changing the long polyimide tube on which the expandable balloon filter is mounted to a short length of polyimide, which is mounted on the wire but can move on the wire between two stops. (Exhibit 38, page 2). This modification has the advantage of facilitating wire movement independent of the filter element.

231. Padraig Maher and Susan Eighan were assigned responsibility for preparing prototypes of the modified filter assembly by April 2, 1998, for evaluation in the Ohki model. (Exhibit 38, page 2).

232. On March 17, 1998, Payne Plastics shipped machined Perspex rod which was required to make the loading funnel. This shipment was received on April 3, 1998. (Exhibit 40).

233. Padraig Maher prepared a specification (SA98 003 revision 02) to describe laser machining of holes in membrane covered acrylic cores used in making balloon filter sacs. (Exhibit 41 dated March 18, 1998).

234. On March 18, 1998, MedNova ordered laser machined coated core parts according to Specification SA98 003, revision 2, from Spectralytics, Inc., a laser machining company. (Exhibit 42). These parts were received on April 6, 1998. (Exhibit 43).

235. On March 26, 1998, Padraig Maher modified the specification for laser machined core parts, based on Spectralytics processing capabilities. (Exhibit 44). Padraig Maher prepared specification SA98 003, revision 3, relating to the acrylic core parts for preparing filter sacs, on March 26, 1998 (Exhibit 45).

236. On March 18, 1998, MedNova ordered UV adhesive from Murphy Engineers (Exhibit 46), for use by Susan Eighan in conducting UV bonding studies (Exhibit 33). This material was shipped on April 6, 1998. (Exhibit 47).

237. Exhibit 48 is a Project Team Meeting Review of the MedNova research team working on development of the embolic filter invention, which took place on March 18, 1998.

238. The attendees at the March 18, 1998 meeting were as follows: Shivaun O'Rourke ("SOR"); Steven Horan ("SH"); Padraig Maher ("PM"); Keith Ryan ("KR"); Jon Hager ("JH"); Susan Eighan ("SE"); Mairsil Claffey ("MC"); and Eamon Brady ("EB"). Copies of the project team meeting review were sent to the project file, maintained by Eamon Brady, as well as David Vale ("DV"), and Paul Gilson ("PG").

239. The general responsibilities of MedNova's research team members working on the embolic filter development project in March 1998 are correctly stated in Exhibit 48.

240. In the week prior to March 18, 1998, Keith Ryan improved process control on the PTFE rig, relating to making the delivery catheter.

241. In the week prior to March 18, 1998, Susan Eighan built filter samples.

242. In the week prior to March 18, 1998, Padraig Maher wrote up Nitinol test results.

243. In the week prior to March 18, 1998, Steven Horan analyzed balloon dip data, evaluated balloon strengths, and ordered cores for preparing filter balloon sacs.

244. Exhibit 48 describes the next week's key goals for team members, in the week following March 18, 1998, as follows.

245. Keith Ryan's key goals included defining a pouch seal process window, resolving Monel wire/PTFE issues, which related to the delivery catheter pod and loading funnel, and building a test product.

246. Shivaun O'Rourke's key goals included approving the pod shrink process validation protocol, which related to the delivery catheter pod, and updating the pod shrink validation.

247. Susan Eighan's key goals included resolving Teflon shrink process issues, which related to the delivery catheter, finalizing the core removal process,

which related to the filter sac, and UV bonding studies, which related to the filter sac bonding to the polyimide tube.

248. Padraig Maher's key goals included retesting the new loading mechanism design for loading the filter element into the delivery catheter, evaluating deployment and retrieval force, and defining a balloon wrap method for the balloon filter.

249. Steven Horan's key goals related to development of the balloon filter, and included dipping balloons for UV bonding trials, reducing the balloon wall thickness, and providing test balloons for Susan Eighan for UV bond testing.

250. On March 19, 1998, MedNova ordered close coiled stainless steel springs from Ashfield Springs, for use in making delivery catheters. (Exhibit 49). These springs were ordered by Padraig Maher. (Exhibit 50). These springs were received on March 31, 1998. (Exhibit 87).

251. On March 19, 1998, Keith Ryan described a procedure for bonding subassemblies to make the filter loading device. (Exhibit 52).

252. From March 18, 1998, to March 20, 1998, Steven Horan prepared a specification (CC97 007, revision 03), describing the 6 mm soluble core used to make filter balloon sacs. (Exhibit 53).

253. From March 18, 1998, to March 20, 1998, Steven Horan prepared a specification (CC97 010, revision 03), describing the 5 mm soluble core used to make filter balloon sacs. (Exhibit 54).

254. On March 19, 1998, Jon Hager prepared a specification (SA98 008 revision 01), describing the filter element, including a polyimide tube and a balloon filter mounted on a Nitinol framework. (Exhibit 55).

255. On March 23, 1998, MedNova ordered heat shrink PTFE tubing, according to specification CB97 002, for use in making delivery catheters. (Exhibit 56).

256. On March 23, 1998, MedNova requested a quote for polyimide tubing from MicroLumen, for use in making filter elements. (Exhibit 57).

257. On March 24, 1998, David Vale prepared drawings of a new modifications of the filter element, having a filter sac supported on self-expanding Nitinol struts, where the filter is mounted on a short section of polyimide tubing. (Exhibit 58). As shown in Exhibit 58, the short section of polyimide tubing has an inner lumen diameter of 0.0145″ and an outer diameter of 0.0185″, and is mounted on a dual diameter guidewire, with a proximal section having a diameter of 0.013″, between a proximal stopper and the distal stopper which permit both distal translation of the guide wire relative to the filter element, and rotation of the guide wire relative to the filter element, which do not displace the filter element. The distal end of the dual diameter guidewire has a diameter of 0.016″.

258. On March 24, 1998, David Vale discussed the use of the modified filter system in the upcoming trial with Paul Gilson and Susan Eighan. (Exhibit 58).

259. On March 24, David Vale, Susan Eighan and Paul Gilson considered that this design would provide excellent wire movement, in that the filter position would not be so much affected by jerky movements when exchanging angioplasty or stent devices over the guidewire. We also considered that this design would eliminate frictional problems with the long polyimide tube support of the filter element. We noted that a larger diameter spring would be required for the delivery catheter shaft. (Exhibit 59). Susan Eighan was to make new Nitinol formers for the redesigned filter element. (Exhibit 58).

260. In a facsimile dated March 24, 1998, Paul Gilson explained to Dr. Gary Roubin our proposed changes to the filter element, which included shortening the polyimide tube of the filter element on which the filter is bonded. Paul Gilson explained that the filter assembly is free to move between pre-determined stops on the guide wire, and thus the wire will be free to torque and to have movement longitudinally. (Exhibit 60). Paul Gilson informed Dr.

Roubin that we would be ready by April 3rd or 4th to evaluate these design changes. (Exhibit 60).

261. On March 24, 1998, MedNova ordered close coiled stainless steel tensioned springs from Ashfield Springs, to make a "pusher" to deploy the filter element, as discussed in Exhibits 58 and 59. (Exhibit 61). These springs were received on March 31, 1998. (Exhibit 62).

262. On March 24, 1998 at the request of Paul Gilson, MedNova received from Tom Kleist of Lake Region Manufacturing a drawing of the custom .013″/.016″ guidewire which they had previously supplied to MedNova. (Exhibit 63).

263. On March 25, 1998, MicroLumen shipped three sizes of polyimide tubing for use in making prototype filter elements according to the modified design. (Exhibit 64).

264. On March 26, 1998, David Vale sent to Paul Gilson an email containing an attachment with three drawings, including a filter element having an internal Nitinol support, a filter sac mounted on the Nitinol support having inlet and outlet holes, a platinum marker band, and a polyimide shaft. The drawings also described a filter delivery catheter, for transluminally inserting the filter element into a vessel, and a retrieval catheter for removing the filter element from the vessel after completing the procedure. (Exhibit 65).

265. On March 26, 1998, Eamon Brady prepared a drawing of an embolic filter protection device, in preparation for filing Irish Application 98 267. (Exhibit 66).

266. On March 26, 1998, MedNova ordered laser machined coated core parts from SpectraLytics, for use in forming filter sac balloons. (Exhibit 67). These parts were shipped on April 7, 1998, and were received on April 14, 1998. (Exhibit 68).

267. On March 27, 1998, David Vale received a price quotation from Adam Spence, for equipment designed to improve welding the soft tip of the retrieval catheter to the retrieval catheter shaft, including the use of a specifically designed radio frequency coil. (Exhibit 69). MedNova ordered this welding unit on March 30, 1998. (Exhibit 70).

268. On March 27, 1998, Jon Hager inspected retrieval catheters produced by Adam Spence Limited. (Exhibit 71). On March 30, 1998, Jon Hager prepared a non-conformance report, concluding that the retrieval catheters were too short. (Exhibit 72).

269. On March 31, 1998, Dawnlough, Ltd. shipped to MedNova pin punch assemblies and units used in the production of filter membranes. (Exhibit 73).

270. On or about April 1, 1998, Eamon Brady prepared a list of design activities to implement the modified embolic filter. (Exhibit 74). These changes included shortening the length of the polyimide tube support for the balloon filter. In order to make this change, it was necessary to prepare a detailed guidewire specification and to specify in detail a proximal stop. Additional design changes to the balloon filter discussed in Exhibit 74 include the use of a tapered filter or stepped filter or grooved filter sac to improve filter performance in undersized vessels. Exhibit 74 also discusses contemplated changes to the delivery catheter, including modifying the attachment of the Touhy Borst connector, increasing the wall thickness of the Teflon shrink cover for the catheter shaft, and modifying the catheter design to permit a force to be applied to the proximal end of the floating filter.

271. On April 1, 1998, David Vale prepared a drawing of the stepped guidewire, having a distal soft tip diameter (E) of 0.018″, and an uncoated proximal diameter F(G) of 0.013″. (Exhibit 75).

272. On April 2, 1998, Eamon Brady informed Paul Gilson of the status of the preparations for the April test in New York using the Ohki model. Following

the March 14, 1998 tests in New York, approximately 35 balloons had been dipped and punched. (Exhibit 77).

273. As described in Exhibit 77, on April 2, 1998, Steven Horan selected a batch of balloons, and carried out a tensile evaluation to prepare the filters for use in the April test.

274. As described in Exhibit 77, on April 2, 1998, Susan Eighan formed Nitinol frame support pieces for the modified filter element.

275. As described in Exhibit 77, on April 2, 1998, David Vale and Keith Ryan worked to build delivery catheters with modified loading mechanisms for the modified filter.

276. As described in Exhibit 77, on April 2, 1998, David Vale also evaluated adhesives to bond a stopper to the guide wire.

277. As stated in Exhibit 77, we worked to have the modified embolic filter systems built by the evening of April 2, 1998, and to evaluate the modified design in a test rig on April 3, 1998, prior to Paul Gilson's departure to New York for the trial.

278. On April 2, 1998, David Vale contacted Lake Region Manufacturing, in a facsimile describing the detailed specification for the stepped guidewire, and requested information concerning the guidewire material and tensile strength, the coating material, the expected strengths of the soft tip and bond, and clearances on the dimensions shown in the drawing. (Exhibits 78, 75).

279. On April 5, 1998, Dr. Gary Roubin conducted tests of the modified design in New York, at Montefiore Hospital. (Exhibit 79), attended by Paul Gilson. In these tests, there were improvements in wire movement in interface, as well as handling of the filter during both preparation and use.

280. The filter of the three NeuroShield embolic filters used in the April 5, 1998 tests in New York are described in a memo from David Vale to Paul Gilson,

Eamon Brady, Padraig Maher, Susan Eighan, Keith Ryan, and the design history file. (Exhibit 81).

281. Exhibit 81 describes the prototype filter that was assembled on April 3, 1998, and tested in New York on April 5, 1998, as having a guide wire having a distal stop ("stopper") mounted on the stepped guidewire having a 0.013″ proximal diameter and a 0.016″ distal tip diameter; a self-expanding filter element mounted on the guidewire proximal of the distal stop, and disposed for translation and rotation on the guide wire between the distal stop and the proximal stop; the filter element having a filter sac of modified geometry mounted on a short polyimide tube, shown in its expanded configuration. The balloon filter was attached to a Nitinol framework having self-expanding struts.

282. The structure of the filter element used in the April 5, 1998, trials in New York is further described in Exhibit 82, which is a page from the laboratory notebook of Padraig Maher made on April 8, 1998.

283. Exhibit 82 confirms that in the modified filter element, the 3 m long polyimide tube support was shortened to be about 40 mm long, which was mounted between two stops (*i.e.*, a proximal stop and a distal stop) on the guide wire. The filter mounted on the polyimide tube floated between the two stops, and was capable of rotation and distal translation on the guidewire. The filter had a membrane sac, affixed to a Nitinol support that was affixed to the polyimide tube. When the guidewire was withdrawn in a proximal direction, the distal stopper at the distal end of the guidewire would abut against the polyimide tube support of the filter.

284. Eamon Brady discussed the results of the trial with Paul Gilson on April 6, 1998, and in an email dated April 6, 1998, Eamon Brady described the results of the second trial on April 5, 1998. (Exhibit 83). This email was sent to

Steven Horan, Padraig Maher, Keith Ryan, David Vale, Susan Eighan, Paul Gilson, and Mairsil Claffey.

285. Exhibit 83 discusses further design changes to the embolic filter system, including improvement of the UV bonding process, used to bond the filter to the polyimide; reducing the frictional coefficient between the polyimide tube support of the balloon filter and the guidewire, to provide free movement between the polyimide and the wire; evaluating a series of filter geometries and selecting the best balloon geometry; testing a polyimide support for the balloon filter; making the proximal filter sac holes larger; and improving the guidewire stiffness.

286. On April 6, 1998, MedNova ordered additional Nitinol tubing from Euroflex, to prepare Nitinol supports for filter elements. (Exhibit 84). The modified design for the Nitinol struts was discussed in a facsimile from David Vale to Euroflex dated April 6, 1998. (Exhibit 84).

287. On April 6, 1998, Jon Hager conducted a quality inspection of retrieval catheters produced by Adam Spence. (Exhibit 85).

288. On April 7, 1998, David Vale requested a quotation from Microgroup for an order of stainless steel cut tube parts, for use as stoppers to be mounted on the guidewire. (Exhibit 86).

289. On April 8, 1998, our Irish Patent Application No. 98 0267 was filed.

290. Throughout the period from just prior to March 5, 1998, until April 8, 1998, Paul Gilson, Padraig Maher, David Vale, Chas Taylor, Eamon Brady, Mairsil Claffey, Susan Eighan, Keith Ryan, Jon Hager, Shivaun O'Rourke, and Steven Horan were engaged in continuous efforts to refine and perfect different elements and features of the prototype embolic protection filter systems and devices discussed herein, in order to demonstrate their practical utility in use in the methods recited in Count 1 and Count 2.

We declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 6th Dec 2005 — Paul Gilson

Date: 9 Dec. 2005 — Eamon Brady

Date: 12th Dec 2005 — Padraig Maher

Date: 9th Dec 2005 — David Vale

Date: 6th Dec 2005 — Chas Taylor